NDA 20-471/S-008

Abbott Laboratories
D-491/AP6B-1
100 Abbott Park Road
Abbott Park, IL 60064-6108

23 APR 2001

Attention: Ernesto J. Rivera
PPD Regulatory Affairs

Dear Mr. Rivera:

Please refer to your supplemental new drug application dated December 22, 2000, received December 26, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyflo Filmtabs (600 mg zileuton tablets).

This "Changes Being Effected" supplemental new drug application provides for revision of the patient information section of the package insert to “Patient Information Leaflet.”

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. David Hilfiker, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research